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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,817	11/20/2003	Xi Chu		9715
7590 05/04/2005			EXAMINER	
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			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,817

Applicant(s)

CHU, XI

Examiner

Urmi Chattopadhyay

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 and 41-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/2/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 4/7/05 has been entered. The changes to the claims have been approved by the examiner.

Election/Restrictions

2. Applicant's election with traverse of Group I, Species (d), claims 29-40 in the reply filed on 4/7/05 is acknowledged. The traversal is on the ground(s) that all four species of Group I are classified under Class 623, subclass 2.42, and therefore the criteria needed to show an undue burden cannot be met. Similarly, all four species of Group II are classified under Class 623, subclass 901, and therefore all four species can be examined without undue burden. This is not found persuasive because the requirement to show a serious burden does not pertain to an election of species, but rather pertains to restriction requirements. Since the claims are directed to independent inventions, election of species is proper pursuant to 35 U.S.C. 121, and it is not necessary to show a separate status in the art or separate classification. See MPEP § 808.01(a). Applicant is reminded that a proper traversal of an election of species is on the grounds that the species are not patentably distinct, wherein evidence now of record showing the species to be obvious variants are submitted or identified by the applicant or clearly admitted on the record that this is the case.
3. The traversal is also on the grounds that, with respect to Group II and Group I being distinct inventions, conventional chemical or electrochemical methods cannot be used to polish

Art Unit: 3738

the valve because the carbon and graphite material are chemically inert. Even if this were to be true, though no evidence was provided to prove that this is the case, the prosthetic valve can be naturally polished by heating to temperatures beyond 1000°C, as is well known in the art.

Additionally, the process as claimed can be used to make another materially different product.

The method of fabricating prosthetic valves does not require the elected embodiment of the trileaflet prosthetic valve to include leaflets having opposed ears. The requirement is still deemed proper and is therefore made FINAL.

4. Claims 1-28 and 41-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups and species, there being no allowable generic or linking claim. Claims 29-40 are being considered for further examination on the merits.

Information Disclosure Statement

5. The Information Disclosure Statement (IDS) filed 3/2/04 has been entered. All cited references have been considered by the examiner except for the third one listed, as indicated by the line drawn through the citation. The U.S. Patent document number is incomplete.

Drawings

6. The drawings are objected to because in FIG. 5e, there are no lead lines from the reference numbers to their respective elements. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or

Art Unit: 3738

figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “prosthesis 510” mentioned on page 14, line 25 is not shown in FIGs. 5a, 5b or any other figure. Also, “triangular hinges 540, 542” mentioned on page 15, line 9 are not shown in any of the figures. It appears that the first occurrence of “425” in FIG. 5g should be changed to --540-- and the second occurrence should be changed to --542--. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The work "invention" on line 1 is legal phraseology that needs to be removed.

9. The disclosure is objected to because of the following informalities:
- a) On page 3, line 17, "paralytic" should be changed to --pyrolytic--.
 - b) On page 8, line 16, "biber" should be changed to --fiber--.
 - c) On page 9, line 24, "grove" should be changed to --groove--.
 - d) On page 9, line 28, "upwnward" should be changed to --upward--.
 - e) On page 10, line 19, it appears that "bileaflet" should be changed to --monoleaflet--.
 - f) On page 14, line 23, "perturtion" should be changed to --protrusion--.
 - g) On page 14, line 31, "(FIG. 5c)" should be changed to --(FIG. 5b)--.
 - h) On page 15, line 1, "(FIG. 5b)" should be changed to --(FIG. 5c)--.
 - i) On page 15, line 14, it appears that "511-515" should be changed to --511, 513, 515--.
 - j) On page 15, line 21, "valvse" should be changed to --valves--.
 - k) On page 15, line 23, "himge" should be changed to --hinge--.

Art Unit: 3738

The specification is replete with spelling errors. Above are just some of the errors that need corrections. It is applicant's responsibility to review the entire specification and make all necessary changes. Appropriate correction is required.

Claim Objections

10. Claims 29, 30, 33, 37 and 38-40 are objected to because of the following informalities:

- a) Claim 29, line 6, "pivotailly" must be changed to --pivotally--.
- b) Claim 30, line 3, the semicolon must be changed to a period.
- c) Claim 33, line 4, "segment" must be changed to --segments--.
- d) Claim 33, "two ears for engaging with the hinges" is repetitive because it is already claimed in claim 29, on which it depends.
- e) Claim 37, line 3, "arotic" must be changed to --aortic--;
line 3, "plumartumy" must be changed to --pulmonary--;
line 3, "tricusular" must be changed to --tricuspid--;
line 3, "transmyocardial" must be changed to --transmyocardial--.
- f) Claim 38, line 1, "prosthetic valves" must be changed to --trileaflet prosthetic valve--.
- g) Claim 39, line 1, "prosthetic valves" must be changed to --trileaflet prosthetic valve--.
- h) Claim 40, line 1, "prosthetic valves" must be changed to --trileaflet prosthetic valve--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 29 recites the limitation "said surface segment" in lines 8-9. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 32 recites the limitation "said support means" in line 2. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests deleting "means" and changing "support" to --supports--.

14. Claim 36 recites the limitation "the pyrolytic carbon" in line 2. There is insufficient antecedent basis for this limitation in the claim. It appears that the claim should be dependent on claim 35 rather than on claim 29, and will so be interpreted for examination purpose.

15. Claim 39 is indefinite because it is unclear what the elements listed as "flat spherical depression, or spherical protrusion" are due to lack of punctuation.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3738

17. Claims 29-34 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Carpentier et al. (USPN 6,039,759).

Carpentier et al. discloses a trileaflet prosthetic valve with all the elements of claim 29. See Figs. 21-23 and column 13, lines 7-58 for a trileaflet prosthetic valve (510) comprising an annular valve body (512) having an inner surface and being disposed around a central axis. Three substantially identical leaflets (526, 527, 528) are mounted in the annular valve body (512) and are configured to translate between a closed position impeding blood flow through the valve and an open position allowing blood flow therethrough. The annular body (512) has three pairs symmetrically placed hinges (522, 524) spaced around an inner surface of the annular body (512) for pivotally supporting the leaflets (526, 527, 528). Each hinge (522, 524), due its shape, has a plane of symmetry containing the central axis. Each of the leaflets have opposed ears (530, 532) for engaging the hinges (522, 524) and a flat edge adjacent each of the ears for engaging a surface segment.

Claims 30 and 33, see Figs. 21 and 23 for each of the leaflets (526, 527, 528) further comprising a central planar surface having a curved outer edge (538) for engaging the inner surface of said annular body (512), an obliquely angled inner edge (536) for engaging adjacent leaflets, two ears (530, 532) for engaging with the hinges, and two flat segments adjacent to each ear (530, 532) to guide the motion of the leaflet.

Claim 31, see Figs. 12-14. The shape of the hinge (522, 524) includes surfaces that provide as stop means for arresting movement of the leaflets.

Claim 32, see Fig. 21 for at least three supports (514') for guiding the leaflets (526, 527, 528), each of the supports comprising two flat planes (514'') on the inner surface of the support.

Art Unit: 3738

Claim 34, see column 6, lines 64-65 for the valve body being formed from pyrolytic carbon and the leaflet substrates being formed from metal (titanium).

Claim 37 recites only an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Because the trileaflet prosthetic valve of Carpentier et al. is a prosthetic heart valve, it is capable of being implanted into a system of heart valves.

Claim 38, see Figs. 12-14 for the shape of the hinges (522, 524) being butterfly.

Claim 39, see Figs. 12-14 for the bottom of the hinges being a spherical depression, as best understood by the examiner.

Claim 40, see Figs. 12-14 for the bottom of the hinges being closed.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3738

19. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carpentier et al. in view of Shu et al. (USPAP 2001/0025197 A1).

Carpentier et al. discloses a trileaflet prosthetic valve with all the elements of claim 29, but is silent to the leaflets being sole pyrolytic carbon or coated with pyrolytic carbon, as required by claim 35. See column 6, lines 64-65 for the valve body being made from pyrolytic carbon and the leaflets being made from titanium. Shu et al. teaches that it is old and well known in the art to coat all exterior surfaces of a valve body and leaflets with pyrolytic carbon in order to provide wear resistant surfaces and insurance against thrombus formation on such surfaces. See paragraph [0006]. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Shu et al. to modify the prosthetic valve of Carpentier et al. by coating the titanium leaflets with pyrolytic carbon in order to provide wear resistant surfaces and insurance against thrombus formation on such surfaces.

Allowable Subject Matter

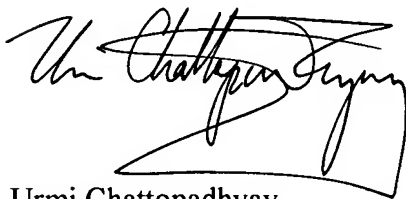
20. Claim 35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

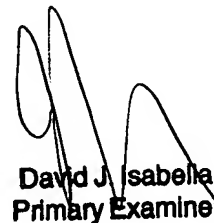
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella
Primary Examiner